Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Application carbohydrate counting application on daily blood sugar control and glycosylated hemoglobin level in children with diabetes type 1

Protocol summary

Study aim
Application carbohydrate counting application on daily blood sugar control and glycosylated hemoglobin level in children with diabetes type 1

Design
A randomized clinical trial with a control group, parallel groups, and a blind strain, on 100 patients with type 2 diabetes. The rand function of Excel software was used for randomization.

Settings and conduct
This study will be conducted in Akbar Hospital in Mashhad. A sugar counting app will be installed for caregivers of control group patients. Before and three months after the intervention in both groups, FBG, 2hpp, and Hb A1C will be taken. The study analyst will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Parents who have a child with type 1 diabetes, Patients with type 2 diabetes for at least three months, The age of a child with diabetes is 1 to 18 years, Literacy for reading and writing, Having a Android smartphone and internet access exclusion criteria: Having other chronic underlying diseases in children

Intervention groups
Intervention group: In this group, an Android app will be installed for parents of children with type 1 diabetes. Parents will record the food consumed by the child during the day in the app. The app will automatically calculate the consumed carbohydrates and the insulin dose of the child (based on the doctor's prescription).Before and three months after installing and using the app, fasting blood glucose (FBG), Two-Hour Postprandial Glucose (2hpp), and Hg A1C will be measured. Control group: There will be no intervention in this group. Only a notebook will be given to parents of children with diabetes to record insulin, FBG, 2hpp, and Hg A1C. In this group, before and three months after receiving the notebook, fasting FBG, 2hpp, and Hg A1C will be measured.

Main outcome variables
fasting blood Glucose, Two-Hour Post Prandial blood Glucose, Glycated hemoglobin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191026045251N3**
Registration date: **2023-03-04, 1401/12/13**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-04, 1401/12/13**
Update count: **0**

Registration date
2023-03-04, 1401/12/13

Registrant information

Name
Mohamad hossein Mafi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3377 2208

Email address
mafimh971@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-21, 1401/09/30

Expected recruitment end date
2023-12-21, 1402/09/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Application carbohydrate counting application on daily blood sugar control and glycosylated hemoglobin level in children with diabetes type 1

Public title
Application carbohydrate counting application
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Parents who have a child with type 1 diabetes Children with at least 3 months history of diabetes The age of a child with diabetes is 1 to 18 years Literacy for reading and writing Having a smart phone and internet access The age of mothers of children with diabetes is between 18 and 60 Consent to participate in the study
Exclusion criteria:
Having other chronic underlying diseases in children with diabetes
Age
From **1 year** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the participants are allocated to the intervention and control groups with Simple Blocked Randomization. The randomized unit is individual. First, blocks of four consisting of control group (2 people) and intervention group (2 people) will be formed. Based on this, 6 different sequences will be formed. After counting the blocks, the blocks will be randomly selected. The random selection continues forever until the sequence is determined for 100 people. The created sequence will be kept in a sealed envelope.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of School of Nursing and Midwifery, Mashhad University of Medical Sciences
Street address
School of Nursing and Midwifery, Gholestan Ave, Doctora Blvd, Mashhad Town
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2022-07-05, 1401/04/14
Ethics committee reference number
IR.MUMS.NURSE.REC.1401.033

Health conditions studied

1

Description of health condition studied
Type 1 diabetes mellitus
ICD-10 code
E10
ICD-10 code description
Type 1 diabetes mellitus

Primary outcomes

1

Description
Fasting blood Glucose
Timepoint
Before and three months after the intervention
Method of measurement
glucometer (Glucose meter)

2

Description
Two-Hour Postprandial Glucose
Timepoint
Before and three months after the intervention
Method of measurement
glucometer (Glucose meter)

3

Description
Glycated hemoglobin
Timepoint
Before and three months after the intervention
Method of measurement
blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: In this group, an Android app will be installed for parents of children with type 1 diabetes. In this app, it is possible to determine the carbohydrate content of the child's food. Parents will record the food consumed by the child during the day in the app. The app automatically calculates the carbohydrates of the food consumed and the dose of insulin the child needs. The calculation formula will be based on the doctor's prescription. Also, the app has a notebook to record insulin and blood glucose fasting and two hours after a meal. In this group, before and three months after installing and using the app, fasting blood glucose levels, two-hour postprandial glucose, and Hg A1C will be measured.

Category
N/A

2

Description
Control group: In this group, parents of children with type 1 diabetes will be given a notebook. In this notebook, parents will record the amount of prescribed insulin, fasting blood glucose levels, two-hour postprandial glucose, and Hg A1C according to the table. The recording of the mentioned markers is based on the doctor's order. In this group, before and three months after receiving the booklet, fasting blood glucose levels, two-hour postprandial glucose, and Hg A1C will be measured..

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Akbar Hospital

Full name of responsible person
Dr. Hossein Mohsenzadeh

Street address
Knowledge and Health City–Shahid Fakouri Blvd-Fakouri #94

City
Mashhad

Province
Razavi Khorasan

Postal code
9177897157

Phone
+98 51 3871 3801

Email
ak.pr@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr Majid Ghayoor Moarhan

Street address
Deputy of Research and Technology, Ghorashi Building, next to Hoveyzeh Cinema, University Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Phone
+98 51 3841 1538

Fax

Email
vcresraech@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Tahereh Sadeghi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
School of Nursing and Midwifery, Ibn Sina Ave, doctora Crossroads, university Blve

City

Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
SadeghiT@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Tahereh Sadeghi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Ibn Sina Ave, doctora Crossroads, university Blve
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
SadeghiT@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Mohamad Hossein Mafi
Position
MSc
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Qazvin University of Medical Sciences, Bahonar Blv
City
Qazvin
Province
Qazvin
Postal code
34197 -59811
Phone
+98 28 3334 4854
Email
mafi1404@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information about main outcome variables is shared.
When the data will become available and for how long
One year after the results are published
To whom data/document is available
Researchers of medical sciences of reputable scientific institutions
Under which criteria data/document could be used
Analysis of the main variable - if there is a need to publish, permission must be obtained from the researchers of the present project.
From where data/document is obtainable
Person responsible for general inquiries email
What processes are involved for a request to access data/document
A maximum of one month after the applicant's email
Comments